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STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

- 1. The standards for coverage of organ transplant services are applied equally to the categorically and medically needy individuals as described in ATTACHMENT 3.1-E, pages 2 through 7.
- 2. The guidelines for approving organ transplants for EPSDT eligible individuals which are not covered under this Plan are as follows:
 - Shall have prior medical authorization a.
 - b. Shall be performed at a Medicare certified facility
 - Shall be an established non-experimental c. procedure
 - d. Shall be medically necessary, specifically:
 - i. The condition is life-threatening and unresponsive to other medical or surgical therapy, with a prognosis of six to twelve months of life.
 - ii. There is significant reason to believe that the transplant will improve the quality of life of the patient.
 - iii. There is significant reason to believe that the patient's medical status is adequate to tolerate the transplant procedure and follow-up medical and surgical care.
 - iv. The initial or primary disease process is confined to the organ with no life threatening involvement of other organ systems and no anticipation that life threatening recurrence of the disease process will involve the transplanted organ or other organ systems.

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- §17-1737-91 <u>General Provisions.</u> (a) Allogenic bone marrow and cadaveric corneal transplants are covered under this program.
- (b) Kidney transplantations are covered under this program.
- (c) Other non-experimental, noninvestigational organ and tissue transplantation are covered when performed in a facility certified by Medicare for the specific transplantation and approved for medical necessity by the department's medical consultants.
- (d) Transplantation shall be performed by experienced specialists with transplantation training and with established success records in an approved Medicare certified facility with proper equipment and adequate and appropriately trained support staff, except as provided in subsection (i).
- (e) Prior authorization shall be required from the department's medical consultant for all transplants.
- (f) Immunosuppressive therapy shall be covered as required.
- (g) If a transplant should fail or be rejected and the patient is still within the age limits for transplantation, the program's medical consultant may review the case for one additional transplantation for that patient.
- (h) The program shall cover costs of tissue typing of potential donors and cost of acquisition of the tissue or organ as well as other studies necessary to determine the appropriateness of the procedure and any post transplantation follow-up evaluations as required.
- (i) When approved by the department's medical consultant, a patient may be treated at an appropriate out-of-state Medicare certified transplant center for the authorized procedure. [Eff 08/01/94; am 11/25/96] (Auth: HRS §346-14; 42 C.F.R. §431.10) (Imp: 42 C.F.R. §440.230; 42 U.S.C.§1396b(i))

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§17-1737-92 Corneal transplant (keratoplasty).

- (a) Indications of penetrating keratoplasty include:
 - (1) Corneal opacification that sufficiently obscures visibility (vision) through the anterior segment of the eye with at least light perception present. Causes for this problem include:
 - (A) Corneal injury and scarring;
 - (B) Corneal degeneration (from Fuch's or other dystrophy or from previous cataract or intraocular lens implantation, or both);
 - (C) Corneal degeneration from keratoconus or familial causes;
 - (D) Corneal infection (e.g., herpes); and
 - (2) Therapeutic graft for relief of pain with at least light perception vision present, from corneal degeneration because of inflammation with pain in the eye and useful vision still present.
 - (b) Indications of lemellar keratoplasty include:
 - (1) Superficial layer corneal scarring and deformity due to:
 - (A) Trauma;
 - (B) Degeneration;
 - (C) Infection; or
 - (D) Congenital deformity (anterior);
 - (2) Aphakia;
 - (3) High myopia;
 - (4) High refractive error;
 - (5) Keratoconus; and
 - (6) Recurrent pterygium.
- (c) Conditions and limitations affecting corneal transplant include:
 - A relative contraindication is intractable glaucoma in the eye under consideration for surgery;

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- (2) No active eye infection at the time of surgery;
- (3) No general medical contraindications to surgery or anesthesia;
- (4) Informed consent shall be obtained from the patient or patient's representative; and
- (5) no age restriction. [Eff 08/01/84] (Auth: HRS §346-14; 42 C.F.R. §431.10) (Imp: 42 C.F.R. §440.230; 42 U.S.C. §1396b (I))

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§17-1737-93 Allogenic bone marrow transplant.

- Indications for allogenic bone marrow transplant (a) include:
 - (1) Severe aplastic anemia unresponsive to usual therapy;
 - (2) Acute myelogenous leukemia in first remission;
 - (3) Acute lymphocytic leukemia in second remission; and
 - (4) Chronic leukemia after first year.
- (b) Conditions and limitations affecting allogenic bone marrow transplant include:
 - Human leukocyte group A (HLA) histocompatible (1) donor shall be available;
 - (2) Patient has no other major systemic disease which would result in poor potential for recovery (such as a heart condition, liver disease, kidney damage, brain lesions, cancer in other organs or lung disease);
 - (3) Patient shall have been properly evaluated by a qualified authorityin Hawaii and bone marrow transplant is recommended as a possible curative procedure or if palliative, with reasonable likelihood for prolongation of life and return to an active life;
 - (4) No active infection at the time of the procedure;
 - No general medical contraindication for the (5) procedure and anesthesia;
 - (6) Informed consent shall be obtained from the patient or the patient's representative; and
 - Age restricted to fifty or under except when (7) identical twin is histocompatible and then age limit may be fifty-five. [Eff 08/01/96] (Auth: HRS §346-14; 42 C.F.R. §431.10) (Imp: 42 C.F.R. §440.230; 42 U.S.C. §1396b(i))

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§17-1737-94 <u>Kidney transplant</u>. (a) Indications are irreversible kidney failure that has progressed to a point that a useful, comfortable life can no longer be sustained by conventional medical treatment. The following conditions may deteriorate tot he point when kidney transplant may be required.

- (1) Glomerulonephritis:
 - (A) Proliferative;
 - (B) Membranous;
 - (C) Mesangio-capilliary;
- (2) Chronic pyelonephritis;
- (3) Hereditary:
 - (A) Polycystic disease;
 - (B) Medullary cystic disease;
 - (C) Nephritis (including Alport's syndrome);
- (4) Hypertensive nephrosclerosis;
- (5) Metabolic:
 - (A) Cystinosis;
 - (B) Amyloid;
 - (C) Gout;
- (6) Congenital:
 - (A) Hyperplasia;
 - (B) Horseshoe kidney;
- (7) Toxic:
 - (A) Analgesic nephropathy;
 - (B) Heavy metal poisoning;
- (8) Irreversible acute renal failure:
 - (A) Cortical necrosis;
 - (B) Acute tubular necrosis; and
- (b) Conditions and limitations affecting kidney transplant include:
 - (1) A living, related donor with major blood group (ABO) and human leukocyte group A (HLA) histocompatibility, or an appropriate cadaveric kidney with major blood group (ABO) and human leukocyte group A (HLA) histocompatibility shall be available;
 - (2) Patient shall be in a stable emotional state;
 - (3) There is no active infection at the time of transplant;

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- (4) There are no general medical contraindications to major surgery and anesthesia;
- (5) Patient has a normal lower urinary tract;
- (6) There are no other major systemic disease which would preclude successful recovery potential (such as cancer, polyarteritis, systemic lupus erythematosis or heart, lung or liver disease);
- (7) Patient is evaluated by a qualified authority in Hawaii and renal transplant is recommended:
- (8) Informed consent shall be obtained from the patient or the patient's representative; and
- (9) Age limits five through fifty. [Eff
 08/01/94] (Auth: HRS §346-14; 42 C.F.R.
 §431.10) (Imp: 42 C.F.R. §440.230; 42
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